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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/822,364

04/12/2004

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S63.2-10866-US01

3075

490 7590 03/11/2009
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EXAMINER

MEHTA, BHISMA

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

03/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/822,364 | Applicant(s) BURGMEIER ET AL. | |
| | Examiner BHISMA MEHTA | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 6-9, 11, 12, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Zamore (U.S. Patent Application No. 2004/0093008). Zamore discloses a dilatation balloon with waist portions, cone portions, and a body portion where the balloon is formed of a first polymeric composition forming a first layer (A) and a second layer (B) is formed on at least a portion of the first layer. The second layer comprises a second polymeric composition which is crosslinked to form a compression region on at least a portion of the balloon. Zamore discloses that the second polymeric composition is crosslinked on at least a portion of the waist portions, the cone portions, or both (paragraph [0300]). Zamore also discloses that the body portion is uncrosslinked as shown in Figure 1B where the body portion of the first layer (A) is shown to be

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uncrosslinked. Zamore discloses that the first polymeric composition of the first layer is a thermoplastic polymer material that is compatible with the first polymeric composition but which is crosslinkable when exposed to crosslinking energy (paragraph [0300]). In paragraph [0088], Zamore discloses the first polymeric composition as being a thermoplastic material including polyolefin, polyethylene terephthalate, or polyether block amide. In paragraphs [0057] and [0088], Zamore disclose the second polymeric composition being a thermoplastic material which is considered to be a thermoset material after crosslinking has occurred and can be selected from the group of polyolefin or polyethylene. As to claim 17, Zamore discloses a dilatation balloon with a first and second waist portion, a first and second cone portion, and a body portion where the balloon is formed of a first polymeric composition that forms a first layer (A) and a second layer (B) on at least one of the cone portions of the balloon formed from a second composition which is crosslinked to form a compression region. Zamore also discloses that the body portion of the balloon is uncrosslinked as shown in Figure 1B where the body portion of the first layer (A) is shown to be uncrosslinked.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 5-9, 11-13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al (U.S. Patent No. 5,344,400) in view of Zamore (U.S. Patent Application No. 2004/0093008). Kaneko et al disclose a dilatation balloon with waist portions (10, 12), cone portions, and a body portion where the balloon is formed of a first polymeric composition forming a first layer (18) and a second layer (16) is formed on at least a portion of the first layer of the balloon. The second layer comprises a second polymeric composition (16). Kaneko et al disclose the second polymeric composition as being selected from the group of olefins or comprising polyethylene. Kaneko et al also disclose a tie layer (17) between a first layer (18) and the second layer (16). In lines 14-26 of column 5, Kaneko et al disclose the first layer or the first polymeric composition as a polyolefin or a polyester. In lines 53-68 of column 5, Kaneko et al disclose a tie layer between the balloon and the catheter shaft. As to claim 17, Kaneko et al disclose a dilatation balloon with a first and second waist portion (10, 12), a first and second cone portion, and a body portion where the balloon is formed from a first polymeric composition that forms a first layer (18) and a second layer (16) on at least one of the first and second cone portions of the balloon formed from a second composition.

Kaneko et al disclose the balloon substantially as claimed. Even though Kaneko et al disclose the second layer being formed on at least a portion of the first layer and the second composition being selected from the group of olefins or comprising polyethylene (lines 47-53 of column 6), Kaneko et al are silent on the specifics of the second polymeric composition being crosslinked to form a compression region and the

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body portion of the balloon being uncrosslinked. Zamore discloses a dilatation balloon with a first layer and a second layer on at least a portion of the first layer where the second polymeric composition is crosslinked. Zamore also discloses that the body portion of the balloon is uncrosslinked as shown in Figure 1B where the body portion of the first or inner layer (A) is shown to be uncrosslinked. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the second layer of Kaneko et al from a polymeric composition which is crosslinkable as taught by Zamore as both Kaneko et al and Zamore teach dilatation balloons with multiple layers and Zamore teaches that it is well known to provide a crosslinkable second layer in order to form balloons with varying degrees of compliancy so that the balloons can be manufactured with compliance characteristics varying from high compliance to low compliance while still having the desired burst strength. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the body portion of Kaneko et al to be uncrosslinked as taught by Zamore as Zamore teaches that it is well known to have an uncrosslinked inner layer so that portions of the inner layer can be easily welded to a catheter shaft. As to claims 7 and 9, even though Kaneko et al disclose the second composition as polyethylene (lines 47-53 of column 6), Kaneko et al are silent on the first polymeric composition comprising a polyether block amide. Zamore discloses a balloon where the first layer comprises a first polymeric composition which is formed of a polyether block amide and a second layer comprising a second polymeric composition which is polyethylene. It would have been obvious to one having ordinary skill in the art at the time the invention

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was made to use for the first polymeric composition of Kaneko et al a polyether block amide as taught by Zamore as both Kaneko et al and Zamore teach balloons with multiple layers and Zamore teaches that it is well known to use polyether block amide for the first layer.

6. Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamore in view of Kaneko et al. Zamore discloses the balloon substantially as claimed. However, Zamore is silent on a tie layer between the first layer and the second layer and a tie layer between the balloon and the catheter shaft. Kaneko et al disclose a tie layer (17) between a first layer (18) and the second layer (16) and a tie layer between the balloon and the catheter shaft. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide between the first layer and the second and between the balloon and the catheter shaft of Zamore a tie layer as taught by Kaneko et al as both Zamore and Kaneko et al teach balloons with multiple layers and Kaneko et al teach that it is well known to provide a tie layer to allow for good adhesion of the first layer to the second layer and of the balloon to the catheter shaft.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zamore in view of Smith et al (U.S. Patent No. 6,083,587). Zamore discloses the balloon substantially as claimed. However, Zamore is silent on the specifics of a tie layer comprising polyethylene modified with at least one member. Smith et al disclose multi-layered polymer structures for medical devices where a tie layer is formed between a first layer and a second layer. In lines 1-22 of column 5, Smith et al disclose the tie layer as comprising a polyethylene modified with maleic anhydride. It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to provide between the first and second layers of Zamore a tie layer comprising polyethylene modified with maleic anhydride as taught by Smith et al as both Zamore and Smith et al teach medical devices with multiple layers and Smith et al teach that it is well known to use a tie layer comprising polyethylene modified with maleic anhydride between the multiple layers for good adhesion of the first layer to the second layer.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al in view of Zamore as applied to claim 6 above, and further in view of Smith et al (U.S. Patent No. 6,083,587). Kaneko et al and Zamore disclose the balloon substantially as claimed. Even though Kaneko et al disclose the tie layer, Kaneko et al are silent on the specifics of the tie layer comprising polyethylene modified with at least one member. Smith et al disclose multi-layered polymer structures for medical devices where a tie layer is formed between a first layer and a second layer. In lines 1-22 of column 5, Smith et al disclose the tie layer as comprising a polyethylene modified with maleic anhydride. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use for the tie layer of Kaneko et al a polyethylene modified with maleic anhydride as taught by Smith et al as both Kaneko et al and Smith et al teach medical devices with multiple layers and tie layers between the multiple layers and Smith et al teach that it is well known to use a polyethylene modified with maleic anhydride for the tie layer.

9. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamore in view of Kaneko et al as applied to claim 13 above, and further in view of

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Samuelson et al (U.S. Patent No. 6,464,683). Zamore and Kaneko et al disclose the balloon substantially as claimed. Even though Kaneko et al disclose the tie layer, Kaneko et al are silent on the specifics of the tie layer comprising a crosslinking inhibitor or the tie layer being formed from a polymeric composition having a lower melting temperature than the first polymeric composition. Samuelson et al disclose multi-layered polymer structures for medical devices where a tie layer (14) is formed between a first layer (12) and a second layer (16). In lines 13-67 of column 7 and in lines 1-14 of column 8, Samuelson et al disclose the tie layer as comprising a crosslinking inhibitor and as having a lower melting temperature than the first polymeric composition of the first layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use for the tie layer of Kaneko et al a crosslinking inhibitor with a lower melting temperature than the first polymeric composition of the first layer as taught by Samuelson et al as both Kaneko et al and Samuelson et al teach medical devices with multiple layers and tie layers between the multiple layers and Samuelson et al teach that it is well known to use a crosslinking inhibitor for the tie layer and to use a tie layer which has a lower melting temperature than the first layer of the device.

10. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al in view of Zamore as applied to claim 13 above, and further in view of Samuelson et al (U.S. Patent No. 6,464,683). Kaneko et al and Zamore disclose the balloon substantially as claimed. Even though Kaneko et al disclose the tie layer, Kaneko et al are silent on the specifics of the tie layer comprising a crosslinking inhibitor or the tie layer being formed from a polymeric composition having a lower melting

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temperature than the first polymeric composition. Samuelson et al disclose multi-layered polymer structures for medical devices where a tie layer (14) is formed between a first layer (12) and a second layer (16). In lines 13-67 of column 7 and in lines 1-14 of column 8, Samuelson et al disclose the tie layer as comprising a crosslinking inhibitor and as having a lower melting temperature than the first polymeric composition of the first layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use for the tie layer of Kaneko et al a crosslinking inhibitor with a lower melting temperature than the first polymeric composition of the first layer as taught by Samuelson et al as both Kaneko et al and Samuelson et al teach medical devices with multiple layers and tie layers between the multiple layers and Samuelson et al teach that it is well known to use a crosslinking inhibitor for the tie layer and to use a tie layer which has a lower melting temperature than the first layer of the device.

Response to Arguments

11. Applicant's arguments with respect to claims 1 and 5-17 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767